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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: 2-Phenylphenol, and salts – Conventional Uses: Revised Occupational and Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED) Document (Case 2575).

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PC Code(s):	064103 – o-Phenylphenol
	064104 – o-Phenylphenol, sodium salt
	064108 – o-Phenylphenol, potassium salt
	064116 – o-Phenylphenol, ammonium salt
EPA MRID No.:	43432901

The following document is the revised occupational and residential exposure assessment and recommendations for conventional uses (postharvest commodity applications only) of ortho-Phenylphenol (OPP), and salts for the RED document. This revised document addresses intermediate-/long-term risks corrected for dermal absorption. The assessment was reviewed by the Health Effects Division's (HED) Science Advisory Council for Exposure (ExpoSAC) to ensure compliance with current HED policy as well as ExpoSAC standard operating procedures (SOPs) for conducting occupational and residential exposure (ORE) assessments.

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Executive Summary

Short- (1-30 days), intermediate- (1-6 months), and long-term (> 6 months) dermal and inhalation risks for occupational handlers using OPP, and salts as a conventional post-harvest fungicide for citrus and pears are not of concern when workers wear baseline personal protective equipment (PPE) (i.e., long-sleeve shirt, long pants, shoes/socks, no respirator) plus chemical-resistant gloves. The following handler scenarios were assessed:

- Mixing/loading (M/L) liquid concentrate solutions for automated post-harvest foaming, dipping, drenching, brushing, spraying treatments;
- Loading ready-to-use (RTU) solutions for automated post-harvest foaming, dipping, drenching, brushing, spraying treatments;
- Loading RTU solution for thermo-fogging post-harvest treatment using an XEDA® Electrofogger; significant dermal and inhalation exposures are not expected for thermo-fogging applications – workers are not present within the storage rooms during the application process;
- Application of solutions by automated foaming, dipping, drenching, brushing, spraying (inhalation exposure only – automated application process results in negligible dermal exposure).

Postapplication scenarios assessed following automated OPP, and salts application to citrus fruits and pears include pre-sorting (citrus only), sorting, and packing. Short- (1-30 days) and intermediate- (1-6 months)/long- (> 6 months) term postapplication dermal and inhalation risks for pre-sorters (citrus only), sorters, and packers are not of concern when workers wear baseline PPE (i.e., long-sleeve shirt, long pants, shoes/socks, no respirator, no chemical-resistant gloves). All dermal risks were calculated with exposures adjusted to the highest labelled application rate (2% solution).

Based on the incident reports, the classification of OPP and its sodium salt as Category I and II acute dermal irritants, respectively, and the absence of acute toxicity data, use of chemical-resistant gloves should be considered for post-harvest activities. Currently, some labels require handlers to wear baseline PPE with chemical-resistant gloves and goggles or a faceshield.

Postapplication dermal and inhalation exposure risks are not of concern for storage room re-entry workers following thermo-fogging applications to pears. The operating instructions for the thermo-fogging machine require application of a self-contained breathing apparatus (SCBA) when entering the cold storage room shortly after application due to low oxygen levels. Use of SCBA will mitigate any potential concerns for OPP, and salts inhalation exposure for workers re-entering the storage room at this time. Additionally, inhalation exposure is considered negligible for those workers entering the storage room months after the application for pear processing and/or distribution preparation. The aerosol fog has likely fully dissipated and the room is ventilated to return it to ambient atmospheric conditions. Postapplication dermal exposure risks for these re-entry workers are considered negligible.

1.0 Background and Purpose

This RED case includes four active ingredients: o-Phenylphenol (OPP) and its salts (sodium, potassium, and ammonium). These ingredients have a variety of antimicrobial uses (i.e., cleaning/disinfectant); however, this assessment only addresses conventional uses of these chemicals – specifically, post-harvest agricultural commodity (citrus and pears only) fungicide applications. There are no residential uses; therefore only occupational exposures will be addressed.

For the purposes of this assessment, only OPP and OPP-sodium salt (SOPP) will be addressed. OPP-potassium salt solely has registered antimicrobial uses and OPP-ammonium salt currently has no active registered products.

2.0 Use Information

Post-Harvest Automated Applications (Dip Tank, Foam, Spray)

OPP and SOPP are used in conventional post-harvest fungicide products formulated as soluble (SC) and emulsifiable concentrates (EC) and RTU solutions. Currently, the registrants (Dow Chemical and Lanxess, Inc.) plan to support uses only for citrus fruits (citron, sweet orange, tangerine, lemon, grapefruit, lime, and kumquat) and pears (Louie, 2005). Of the two post-harvest fungicide products with OPP as the active ingredient, one has been cancelled (2792-35; cancelled 21JUL05), and the other (43410-9) is not labelled for use on citrus or pears. As such, only products with SOPP as the active ingredient are currently labelled for these uses and are, therefore, the focus of this assessment.

Typical application methods were derived from the labels and/or Agency knowledge of use practices and include bin drenching, flooding, dipping, waxing, foam washing, and spraying over rolling brushes. Application of SOPP solutions are typically automated with commodities passing through sprays/foams/brushes on conveyor belts or bins being mechanically dipped. The commodities are then manually sorted and packed by workers at the end of the process.

Thermo-fogging

An additional end-use-product (EUP), formulated as a RTU solution is labeled for use on pears in cold storage only with the XEDA® Electrofogger, a thermo-fogging device. The label indicates that applications should strictly follow the machine's operating instructions.

Prior to treatment, cooling systems and humidifiers and circulation fans are turned off. Tubing suctions the product directly from the bung or spout of an open pail to the machine, which is outside the storage room. A rigid pipe and nozzle extending from the machine is attached to the storage room through an access hatch and further sealed with plastic sheeting and duct tape. The machine flash heats the liquid to 165 - 170°C in a fast flow of air which is dispersed as a fog of extremely small particles. Once the fogger is operational, an operator/monitor stays with the fogger to insure it is working properly. At no time during the application process is anyone permitted inside the storage room. The fogging process takes about 1 hour to treat 125 tons and approximately 3 hours to treat 400 tons of fruit. An operator will not treat more than two rooms per day. After treatment, the storage room is kept at 32 – 36°F and 1-3% oxygen for a period of 2 weeks to 4 months, at which time the fruit is scheduled for processing and/or distribution (Collantes, 2005).

Chemical-specific information regarding daily amount treated (i.e., pounds of fruit treated per day) is not available. However, use information from similar post-harvest active ingredients previously assessed (i.e., imazalil, thiabendazole, ethoxyquin, and diphenylamine) will be used in this assessment.

There are currently 9 active SOPP labels. Label directions for the liquid concentrate formulations call for dilution in water. Application rates are calculated as pounds of active ingredient per gallon of dilute solution (i.e., lb ai/gal soln) ranging from 0.0066 to 0.19 lb ai/gal soln (0.05 – 2% solution by weight). Other labels further list the amount of fruit per gallon of dilute solution (i.e., lbs fruit/gal soln); this ranges from 3,000-10,000 pounds lbs fruit/gal soln depending on the concentration. The RTU thermo-fogging product has an application rate of 0.0633 lb ai/2200 lbs fruit. Appendix A has a more detailed summary of these products.

3.0 Hazard Identification

Note: Hazard Identification section was provided by the Antimicrobials Division (AD).

The acute toxicity database for OPP, and salts is considered incomplete. Acute dermal toxicity (870.1200), acute inhalation toxicity (870.1300), and primary eye irritation studies must be submitted. OPP has a moderate order of acute toxicity via the oral route of exposure (Toxicity Category III). For dermal irritation, OPP and its sodium salt are severe (Toxicity Cateogry I) and moderate to severe (Toxicity Category II) irritants, respectively. OPP and its sodium salt are not dermal sensitizers. The acute toxicity data for OPP and salts is summarized below in Table 1.

Table 1: Acute Toxicity Profile for OPP, and salts

Guideline Number	Study Type/ Test substance (% a.i.)	MRID Number/ Citation	Results	Toxicity Category
870.1100 (§81-1)	Acute Oral Toxicity - Rat 2-phenylphenol, purity 99.9%	43334201	LD_{50} = 2733 mg/kg	III
870.1100 (§81-1)	Acute Oral Toxicity - Rat 2-phenylphenol, sodium salt purity 99.1%	433342402	LD_{50} = 846 mg/kg (male) LD_{50} = 591 mg/kg (female)	III
870.1200 (§81-2)	Acute Dermal Toxicity	NS	NS	---
870.1300 (§81-3)	Acute Inhalation Toxicity	NS	NS	---
870.2400 (§81-4)	Acute Eye Irritation	NS	NS	---

Table 1: Acute Toxicity Profile for OPP, and salts				
Guideline Number	**Study Type/ Test substance (% a.i.)**	**MRID Number/ Citation**	**Results**	**Toxicity Category**
870.2500 (§81-5)	Acute Dermal Irritation- Rabbit 2-phenylphenol purity 99.9%	43334202	Dermal irritant	I
870.2600 (§81-6)	Dermal Sensitization - Guinea pig 2-phenylphenol, purity 99.9%	43334203	Non sensitizer.	NA
870.2600 (§81-6)	Dermal Sensitization - Guinea pig 2-phenylphenol, sodium salt purity 99.1%	43334205	Non sensitizer.	NA

Table 2: Summary of Toxicological Doses and Endpoints for OPP, and salts for Use in Human Risk Assessments			
Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE, UF, Special FQPA SF, for Risk Assessment	Study and Toxicological Effects
Dietary Risk Assessments			
Acute Dietary (general population and females 13-49)	No appropriate endpoints were identified that represent a single dose effect. Therefore, this risk assessment is not required.		
Chronic Dietary (all populations)	**NOAEL** = 39 mg/kg/day	**FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation) **Chronic RfD** = 0.39 mg/kg/day **Chronic PAD** = 0.39 mg/kg/day	Combined oral toxicity/carcinogenicity study in rats (MRID 43954301, 44852701, 44832201) LOAEL of 200 mg/kg/day based upon decreased body weight, body weight gain, food consumption and food efficiency, increased clinical and gross pathological signs of toxicity.
Non-Dietary Risk Assessments			
Incidental Oral Short-Term (1 - 30 days)	**NOAEL (maternal)** = 100 mg/kg/day	**Target MOE** = 100 **FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation)	Developmental (gavage) toxicity studies in rats (MRID 00067616, 92154037) and rabbits (MRID 41925003; co-critical developmental toxicity study) Maternal LOAEL of 300 mg/kg/day based upon clinical observations of toxicity, decreased weight gain, food consumption and food efficiency observed in the rat developmental toxicity study.
Incidental Oral Intermediate-Term	**NOAEL** =	**Target MOE** = 100 **FQPA SF** = 1	Combined oral toxicity/carcinogenicity study in rats (MRID 43954301, 44852701, 44832201)

Table 2: Summary of Toxicological Doses and Endpoints for OPP, and salts for Use in Human Risk Assessments			
Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE, UF, Special FQPA SF, for Risk Assessment	Study and Toxicological Effects
(1 - 6 months)	39 mg/kg/day	UF = 100 (10x inter-species extrapolation, 10x intra-species variation)	LOAEL of 200 mg/kg/day based upon decreased body weight, body weight gain, food consumption and food efficiency, increased clinical and gross pathological signs of toxicity.
Dermal Short-Term (1 - 30 days) (residential and occupational)	**NOAEL (dermal)** = 100 mg/kg/day	**Target MOE** = 100 **FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation)	21-Day Dermal toxicity study in rats (MRID 42881901) LOAEL (dermal) of 500 mg/kg/day based upon dermal irritation (erythema, scaling) at the site of test substance application.
Dermal Intermediate- and Long-Term (1 - 6 months and >6 months) (residential and occupational)	**NOAEL** = 39 mg/kg/day[a]	**Target MOE** = 100 **FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation)	Combined oral toxicity/carcinogenicity study in rats (MRID 43954301, 44852701, 44832201) LOAEL of 200 mg/kg/day based upon decreased body weight, body weight gain, food consumption and food efficiency (effects observed as early as 13 weeks in this study), increased clinical and gross pathological signs of toxicity.
Inhalation Short-Term (1 - 30 days) (residential and occupational)	**NOAEL (maternal)** = 100 mg/kg/day[b]	**Target MOE** = 100 **FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation) **DB UF** = an additional 10x is necessary for route extrapolation. If results are below an MOE of 1,000, a confirmatory inhalation study is warranted.	Developmental (gavage) toxicity studies in rats (MRID 00067616, 92154037) and rabbits (MRID 41925003; co-critical developmental toxicity study) Maternal LOAEL of 300 mg/kg/day based upon clinical observations of toxicity, decreased weight gain, food consumption and food efficiency observed in the rat developmental toxicity study.
Inhalation Intermediate- and Long-Term (1 - 6 months and >6 months) (residential and occupational)	**NOAEL** = 39 mg/kg/day[b]	**Target MOE** = 100 **FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation) **DB UF** = an additional 10x is necessary for route extrapolation. If results are below an MOE of 1,000, a confirmatory inhalation	Combined oral toxicity/carcinogenicity study in rats (MRID 43954301, 44852701, 44832201) LOAEL of 200 mg/kg/day based upon decreased body weight, body weight gain, food consumption and food efficiency (effects observed as early as 13 weeks in this study), increased clinical and gross pathological signs of toxicity.

Table 2: Summary of Toxicological Doses and Endpoints for OPP, and salts for Use in Human Risk Assessments			
Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE, UF, Special FQPA SF, for Risk Assessment	Study and Toxicological Effects
		study is warranted.	
Cancer (oral, dermal, inhalation)	**Classification:** *ortho*-Phenylphenol is classified as "Not likely to be carcinogenic below a specific dose range", without quantification of risk.		

UF = uncertainty factor, DB UF = data base uncertainty factor, FQPA SF = special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, MOE = margin of exposure
[a]A human dermal absorption factor of 43% is used because an oral endpoint was selected for the intermediate- and long-term dermal exposure scenarios.
[b]The inhalation absorption factor of 100% (default value, assuming oral and inhalation absorption are equivalent) should be used since an oral endpoint was selected for the inhalation exposure scenarios.

Short-term dermal and inhalation risks are calculated separately. Intermediate- and long-term dermal and inhalation risks can be combined due to a common toxicological endpoint; however, they are presented separately so a determination can be made for additional inhalation toxicity data. Table 2 notes that for inhalation risks, MOEs below 1000 warrant additional toxicity data. Table 3 below shows a summary of the levels of concern for each route of exposure and exposure duration.

Table 3: Levels of Concern for OPP, and salts		
Occupational (Worker) Exposure		
Route	**Short-Term**	**Intermediate- and Long-Term**
	MOE	**MOE**
Dermal	100	100
Inhalation	100*	100*

*MOEs below 1000 may warrant confirmatory inhalation toxicity data. See Table 2.

4.0 Incident Report

No post-harvest commodity fungicide application-related incidences were reported in the incident report. All reports were associated with surface disinfectants. However, all reports indicated dermal, oral, and ocular irritation. The report notes that because the effects are reported with products containing ingredients other than OPP, and salts, it cannot rule out the possibility that some of the effects are caused by other ingredients (Chen, 2005).

5.0 Occupational Exposure and Risk Assessment

It has been determined that there is the potential for exposure in occupational scenarios from handling SOPP/OPP products during the application process and from conducting activities in areas previously treated with SOPP/OPP. As a result, risk assessments have been completed for both handler and postapplication scenarios.

5.1 Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is a potential for exposure to handlers (mixers, loaders, applicators, flaggers, etc.) during use or to persons entering treated sites after application is complete. Toxicological endpoints were selected for short-, intermediate-, and long-term exposures to SOPP. Risk assessments are required for occupational handlers and occupational postapplication exposures that can occur as a result of OPP, and salts use.

5.2 Occupational Handler Exposures and Risks

The Agency uses the term "handlers" to describe those individuals who are involved in the pesticide application process. The agency believes that there are distinct job functions or tasks related to applications and that exposures can vary depending on the specifics of each task. Job requirements (e.g., amount of chemical to be used in an application), the kinds of equipment used, the crop or target being treated, and the circumstances of the user (e.g., the level of protection used by an applicator) can cause exposure levels to differ in a manner specific to each application event. Handler tasks can generally be categorized using one of the following terms:

- Mixer/loaders
- Applicators
- Mixer/loader/applicators
- Flaggers

5.2.1 Occupational Handler Exposure Scenarios

Potential exists for dermal and/or inhalation exposure during the following occupational handler scenarios:

- M/L liquid concentrate solutions for post-harvest foaming, dipping, drenching, brushing, spraying treatments;
- Loading RTU solutions for post-harvest foaming, dipping, drenching, brushing, spraying treatments;
- Loading RTU solution for thermo-fogging post-harvest treatment using an XEDA® Electrofogger; significant dermal and inhalation exposures are not expected for thermo-fogging applications – workers are not present within the storage rooms during the application process;
- Application of solutions by foaming, dipping, drenching, brushing, spraying. *Note: this scenario is not a typical "applicator" scenario. The assessment for automated application estimates exposures and risks (inhalation exposure only – automated application process results in negligible dermal exposure) for workers in the vicinity of the application process.*

5.2.2 Data and Assumptions for Occupational Handler Exposure Scenarios

A series of assumptions and exposure factors served as the basis for completing the occupational handler risk assessments. Each assumption and factor is detailed below.

- It is anticipated that most of the occupational OPP, and salts exposure will generally occur in a short- and intermediate-term pattern, given that most uses are for controlling disease outbreaks after the harvest and most crops are not harvested longer than 6 months. There may be potential for long-term exposures due to some citrus harvests lasting over 6 months (California Citrus Quality Council, California Citrus Crop Profile, 2003). However, the endpoint is the same for intermediate- and long-term dermal and inhalation exposures, respectively, and the assessment of intermediate-term risk is considered protective for long-term risk.
- The Agency always considers the maximum application rates allowed by labels in its short-, intermediate-, and long-term risk assessments in order to consider what is legally possible based on the label.
- A typical workday is assumed to be 8 hours per day.
- Adult breathing rate is assumed 1.6 m^3 per hour (for moderate activities).
- Adult body weight used in risk calculations is 70 kg;
- Assumptions for amount treated per day (i.e., lbs fruit/day or gal soln/day) values were taken from previously assessed active ingredients (i.e., imazalil, thiabendazole, ethoxyquin, and diphenylamine) used in similar post-harvest applications. Further refinement of this assessment is possible with crop/chemical-specific information.

    - Citrus: 1,440,000 lbs/day
        - 2000 boxes/hr * 90 lbs/box * 8 hrs/day
    - Pears: 500,000 lbs/day
        - amount of citrus treated per day is assumed to be more conservative and is used in risk calculations; however the assessment for diphenylamine assumed 500,000 lbs pears/day for a truck drencher application

- Baseline PPE: includes typical work clothing (i.e., a long-sleeved shirt, long pants, shoes, socks, and no respiratory protection). It does not include chemical-resistant gloves.
- Baseline/Gloves PPE: includes chemical-resistant gloves in addition to baseline PPE. *Note: most labels call for handlers to don at least this level of protection.*

<u>Unit Exposure Data Sources</u>

Many of the unit exposures used in this assessment were based on the PHED Version 1.1 of August 1998. The unit exposures from PHED that were used to complete all of the aspects of this risk assessment are discussed below.

Pesticide Handler Exposure Database (PHED) Version 1.1 (August 1998): It is the policy of HED to utilize the data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when no chemical-specific data are provided. Data from PHED were used to complete this assessment.

PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts – a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates) and HED has developed a series of tables of standard unit exposures for many occupational scenarios that can be utilized to ensure consistency in exposure assessments. These values are included in the "PHED Surrogate Exposure Guide".

The unit exposures calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases.

Chemical-specific Data Sources for Handler Activities

A study designed to evaluate potential postapplication exposures of workers to SOPP/OPP during post-harvest pear and citrus fruit handling activities was conducted by Dow Chemical to fulfill a portion of the data requirements requested by the Agency in a Data Call-In (DCI) in 1992. A protocol of the study was reviewed and comments and recommendations were made by HED (Morris, 1993). The submitted study (MRID 43432901), completed in 1994, is titled "Evaluation of Postapplication Exposures to Sodium o-Phenlyphenate Tetrahydrate/o-Phenylphenol to Workers During Post-Harvest Activities at Pear and Citrus Fruit Packaging Facilities."

The study, mainly designed to evaluate postapplication activities (i.e., sorters and packers), included area (i.e., background) air monitoring data. It is assumed that this data captured SOPP/OPP air concentrations during the automated application process and will be used to quantitatively assess inhalation risk for process-area workers during this process (dermal exposure during the automated application process is considered negligible). It should be noted that the stated intention of the area monitoring was *not* for quantitative assessment of inhalation exposures during application. It was determined, however, that this data, although mostly collected in the sorting/packing areas, provided a reasonable representation of inhalation exposure for workers in the vicinity of the operation during the application process.

The following is an overall description of the study including a detailed review of the results of area air monitoring. Discussion and review of postapplication dermal and inhalation exposure data is in Section 5.3.1.

- **MRID 43432901:** Evaluation of Post-Application Exposures to Sodium o-Phenylphenate Tetrahydrate/o-Phenylphenol to Workers During Post-Harvest Activities at Pear and Citrus Fruit Packaging Facilities, 1994.

This study was conducted to determine postapplication dermal and inhalation exposures to workers following the application of SOPP/OPP solutions to citrus fruits and pears. A total of 62 participants in 6 facilities (located in Washington, Florida, and California) were monitored for dermal and inhalation exposure in this study. The following table details the breakdown of replicates.

Table 4: MRID 43432901 – Replicate Breakdown

Facility #	Location(s)	Automated Application Type	Application Rate (% soln)	Activities Monitored (at each facility)	Total # Replicates
1, 2, 3	Peshatin, Cashmere (WA)	Dip Tank	0.204% (avg) 0.238% (max, Facility 3)	5 Pear Sorters 5 Pear Packers	30* *two alternate replicates at Facility 2 with some uncollected data
4	Ft. Pierce (FL)	Foam	0.543%	2 Citrus Pre-Sorters 3 Citrus Sorters 5 Citrus Packers	10
5, 6	Orange, Redlands (CA)	Spray	1.03% (avg) 1.29% (max, Facility 6)	2 Citrus Pre-Sorters 3 Citrus Sorters 5 Citrus Packers	20

All application solutions were prepared using SOPP formulations; however, different concentrations (i.e., application rates) were used in each facility. Samples of formulations were analyzed at each facility and showed a range of 0.140 to 1.29% (averages, expressed as % OPP by weight). The maximum labeled application rate is 2%.

After treatment (by automated dip, foam, or spray) the citrus or pears were conveyed to a pre-sort station where workers would pull out culls (i.e., damaged fruit). It should be noted that only workers performing pre-sorting activities for citrus fruits were monitored. Fruits finally reached the sorters and packers after being cleaned, waxed, and dried.

Sorters separated the citrus/pears into different grades based on appearance, quality, and size. Packers in the pear facilities performed all activities (i.e., wrapping, boxing) manually, while packers in two citrus facilities operated packing machines and performed manual work. Approximately 180-300 boxes (40-50 pounds per box) of pears are packaged per day. Similar information was not provided for citrus packers.

Area air monitoring was conducted only in the three citrus facilities using a polyvinyl chloride (PVC) filter in a plastic cassette and a silica gel sorbent tube. This data was conducted to evaluate ambient air concentrations of SOPP/OPP in areas occupied by postapplication workers; the data was intended to augment the actual worker exposure data. Preliminary data from the pear segment of the study (conducted prior to the citrus segment) suggested that additional area monitoring data might better define sources of potential exposure. It is noted that the intention of this data was not to represent worker exposure data. However, it is believed that because the application process is automated, but workers are present in the vicinity of the process, this data represents the best approximation for exposure during the application process.

The following table presents a summary of the results of the area monitoring in the citrus facilities. Results have been corrected for field fortification recoveries below 100% and are expressed as a time-weighted average (TWA) in micrograms per cubic meter (ug/m^3).

Table 5: Area Monitoring in Citrus Facilities

Facility #	Concentration (ug/m^3)[1]
4	23.1
5	11.8
6	90.3
All	38.6

[1] All concentrations are arithmetic means expressed as a TWA.

5.2.3 Occupational Handler Exposure and Risk Calculation Methods

Calculation Methods using Unit Exposures

The Agency uses a concept known as unit exposure as the basis for assessing handler exposures. The unit exposure is amount of exposure that occurs while handling a pound of active ingredient. Daily exposures are calculated by considering application parameters (i.e., rate and area treated) along with unit exposure levels. Exposures are then normalized by body weight to calculate dose levels and the Margin of Exposure (MOE).

Daily Exposure: The daily exposures to handlers are calculated as described below. The first step is to calculate daily exposure (dermal or inhalation) using the following formula:

Daily Exposure = Unit Exposure x Application Rate x Amount Treated

Where:

Daily Exposure	=	Amount deposited on the surface of the skin or amount that is inhaled (mg ai/day);
Unit Exposure	=	Normalized exposure value, derived from August 1998 PHED Surrogate Exposure Table and various referenced exposure studies (mg ai/lb ai);
Application Rate	=	Amount of a.i. applied per unit treated such as acres or pounds of seed
Amount Treated	=	Typically expressed as acres/day for crops and pounds/day for seed.

Inhalation exposure values (for mixers/loaders, only) are calculated in a similar manner. The only difference is that unit exposures representing the inhalation route are calculated using PHED and standard human breathing rates (29 liters/minute and an 8 hour exposure).

Daily Dose: Daily dose (inhalation or dermal) are then calculated by normalizing the daily dermal exposure value by body weight. It should be noted that short-term dermal exposures need not be corrected for dermal absorption (i.e., dermal absorption factor) because the dermal endpoint was based upon a dermal study. Intermediate-/long-term dermal exposure/risk calculations are based on an oral endpoint, and are corrected for absorption using a 43% dermal absorption factor. The inhalation absorption factor is assumed to be 100 percent because the inhalation endpoint was based upon an oral study. Daily dose is calculated using the following formula:

$$\textbf{Average Daily Dose}\left(\frac{mg}{kg/day}\right) = \textbf{Daily Exposure}\left(\frac{mg.ai}{day}\right)\ \mathbf{x}\left(\frac{absorbtionfactor(\%/100)}{Bodyweight(kg)}\right)$$

Where:

Average Daily Dose	=	The amount as absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day);
Daily Exposure	=	Amount deposited on the surface of the skin that is available for dermal absorption or amount that is inhaled (mg ai/day);
Absorption Factor	=	43% dermal absorption factor for int/long-term calculations 100% for inhalation exposures (all durations)
Body Weight	=	70 kg representing the general adult population.

Margins of Exposure: Finally, the daily dermal dose and daily inhalation dose received by handlers are compared to the appropriate endpoint (i.e., NOAEL or LOAEL) to obtain a Margin of Exposure (MOE). All MOE values were calculated separately for dermal and inhalation exposures using the formula below:

$$\textbf{MOE = NOAEL/ADD}$$

Where:

MOE	=	Margin of exposure
ADD	=	Average Daily Dose (mg ai/kg/day) or the amount as absorbed dose received from exposure to a pesticide in a given scenario
NOAEL	=	No Observed Adverse Effects Level (mg ai/kg/day).

<u>Calculation Methods using Chemical-Specific Data</u>

Ambient area monitoring was used to quantitatively assess exposure to workers during the application process. As discussed previously, this data best represents exposure to workers in the vicinity of the automated application process, although the samples collected were in the area where workers conduct postapplication activities (i.e., sorting and packing).

The study data presents exposure as a TWA concentration in micrograms per cubic meter. This concentration must be converted into an average daily exposure (mg/kg/day) to be used in the MOE calculation described above. To present the area monitoring data as an average daily dose, the following calculation is used.

$$\textbf{Avg Daily Dose}\left(\frac{mg}{kg/day}\right) = \textbf{Daily Exp.}\left(\frac{ug}{m3}\right)\ \mathbf{x\ Inhl.\ Rate}\left(\frac{m3}{day}\right)\mathbf{x}\left(\frac{absfactor(\%/100)}{Bodyweight(kg)}\right)\mathbf{x}\left(\frac{(1mg)}{(1000ug)}\right)$$

Where:

Average Daily Dose = The amount as absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day);
Daily Exposure = Area monitoring TWA concentration (ug/m^3);
Inhalation Rate = Adult daily inhalation rate: 8 hrs/day * 1.6 m^3/hr = 12.8 m^3/day;
Absorption Factor = 100% for inhalation exposures (all durations);
Body Weight = 70 kg representing the general adult population.

5.2.4 Occupational Handler Risk Estimates

With the use of chemical-resistant gloves (i.e., Baseline/Gloves PPE), short-term dermal risks are not of concern for handlers. Short-term inhalation risks are not of concern at baseline PPE (i.e., no respiratory protection). Intermediate-/long-term dermal risks are not of concern when chemical-resistant gloves are used and intermediate-/long-term inhalation risks are not of concern at baseline PPE. Tables 6 and 7 below summarize the handler risk estimates. Detailed exposure and risk calculations are in Appendix B.

Table 6: Short-term Dermal and Inhalation Risks for OPP, and salts Handler Activities

Exposure Scenario	Crop	Application Rate (lb ai/lb fruit)	Short-term Risk		
			Dermal MOE (Target MOE = 100)		Inhalation MOE (Target MOE = 100*)
			Baseline	Baseline/Gloves	Baseline
Mixing/Loading & Loading					
Mixing/loading EC/SC for Automated Post-harvest Applications	Citrus & Pears	0.0000633	26	3300	64000
Loading RTU for Automated Post-harvest Applications	Citrus only	0.0000133	130	16000	300000
Loading RTU for Thermofogging applications	Pears only	0.0000288	58	7300	140000
Automated Application Process					
Activities during automated application (i.e., operations monitoring)	Citrus & Pears Citrus only	NA	Negligible		6100

*MOEs below 1000 may warrant confirmatory inhalation toxicity data. See Table 2.

Table 7: Intermediate-/Long-term Dermal and Inhalation Risks for OPP, and salts Handler Activities

Exposure Scenario	Crop	Application Rate (lb ai/lb fruit)	Intermediate-/Long-term Risk		
			Dermal MOE (Target MOE = 100)		Inhalation MOE (Target MOE = 100*)
			Baseline	Baseline/Gloves	Baseline
Mixing/Loading & Loading					
Mixing/loading EC/SC for Automated Post-harvest Applications	Citrus & Pears	0.0000633	24	3000	25000
Loading RTU for Automated Post-harvest Applications	Citrus only	0.0000133	110	14000	120000

Loading RTU for Thermofogging applications	Pears only	0.0000288	53	6700	55000
Automated Application Process					
Activities during automated application (i.e., operations monitoring)	Citrus & Pears	NA	Negligible		2400
	Citrus only				

*MOEs below 1000 may warrant confirmatory inhalation toxicity data. See Table 2.

5.2.5 Occupational Handler Risk Characterization

The exposure data that were used in the SOPP/OPP occupational handler risk assessment represents the best data currently available. In many cases, the Pesticide Handlers Exposure Database (PHED) was used to develop the unit exposures. In addition to PHED, the Agency used a few literature and registrant submitted studies to define unit exposures. Generally, the quality of these studies is excellent. PHED unit exposures represent a central tendency of the data that ranges from the geometric mean to the median or arithmetic mean of the data (it depends upon the distribution of the data). As such, the values based on the recent studies also are measures of central tendency (e.g., the geometric means were selected from each study for assessment purposes in most cases).

Other inputs for this assessment included chemical-specific data, application rates, and daily amount treated (i.e., lbs fruit treated/day). The application rate used was the maximum labeled rate. The daily amount treated, as seen in other post-harvest commodity assessments, was based on a typical citrus fruit facility – and is considered a conservative estimate. The inhalation exposure used for "application" exposure was ambient area monitoring data from a submitted study, not personal monitoring data. Because the application process is automated, workers do not perform application activities *per se*; this data was considered a reasonable estimate of inhalation exposure to workers in the vicinity of the application process. Additionally, the value used (90.3 ug/m^3) was the maximum average exposure concentration from a California citrus facility (Facility #6). The overall average concentration for citrus facilities was much lower (38.6 ug/m^3). Ambient area monitoring was not conducted in pear facilities.

A summary of the input values is given in Table 8.

Table 8: Summary of Handler Input Values

Input Value	Source	Comments
Daily Amt. Treated (lbs citrus/day)	From previously assessments of chemicals with post-harvest applications (i.e., imazalil, thiabendazole, ethoxyquin, and diphenylamine)	Citrus value is assumed to be a conservative estimate.
Unit Exposure Data	PHED	Most values are geometric mean, not upper percentile.
Automated Post-harvest Application Inhalation Exposure	MRID 43432901	The data for area monitoring was used as a reasonable surrogate of inhalation exposures during the automated application process. The highest average (from Facility 6) was used to

Table 8: Summary of Handler Input Values		
Input Value	**Source**	**Comments**
		provide the most conservative estimate.
Application Rate	EPA Registration # 64864-54	This was the highest application rate of the two liquid concentrate products that specified the amount of fruit to treat with said rate. It is also the highest % soln of all labels (2%).

5.2.6 Recommendations for Occupational Handler Assessment

All labels should require the use of chemical-resistant gloves when handling SOPP/OPP. As noted in Section 3.0, there is currently no acute eye, dermal, or inhalation toxicity studies, so application of protective equipment based on acute toxicity categories cannot be determined (although it is recognized that this use does not fall under Worker Protection Standard (WPS) provisions). Based on this handler assessment, however, chemical-resistant gloves are warranted. Currently 4 of the 9 active labels require chemical-resistant gloves. See Appendix A for more label information.

Additionally, labels should specify the amount of fruit to treat with the specified application rates. Currently 3 of the 9 active labels have this additional statement.

5.3 Occupational Postapplication Exposure and Risk Assessment

The Agency uses the term "postapplication" to describe exposures to individuals that occur as a result of working in an environment that has been previously treated with a pesticide. The Agency believes that there are distinct job functions or tasks related to the kinds of activities that occur in previously treated areas such as harvesting vegetables in a treated field.

In the case of SOPP/OPP post-harvest commodity applications, workers performing sorting and packing activities are potentially exposed to SOPP/OPP following application. Additionally, potential dermal and inhalation exposures exist for storage room re-entry workers following thermo-fogging applications performing post-treatment residue sampling and for workers transporting treated pears from the storage room to be processed and/or distributed.

5.3.1 Data Used for Occupational Postapplication Exposure Scenarios

Postapplication data has been submitted for use in determining postapplication exposures and risks for workers performing sorting and packing activities. No data is currently available to quantitatively assess postapplication exposures to storage room re-entry workers following thermo-fogging applications.

The study previously summarized in Section 5.2.2 determined dermal and inhalation exposure monitoring through passive dosimetry for workers performing sorting and packing activities following application of SOPP/OPP solutions to citrus fruits and pears. The following is a summary and discussion of results of the postapplication dermal and inhalation exposures.

As previously discussed, the citrus fruits and pears reach the sorters and packers following application of the SOPP/OPP solution, a pre-sorting phase, a cleaning/waxing phase, and a drying phase. The sorters then separate the citrus/pears into grades which the packers package both manually (in the case of both citrus fruits and pears) and mechanically (in the case of citrus only). The study conducted dermal (arms, hands, torso) and inhalation (personal breathing zone) exposure monitoring during these activities. The study noted that during pre-survey observations, it was visually apparent that there was a lack of contact with treated fruit with lower portions of the body; therefore only upper-body exposures were determined.

Dermal exposure to the torso region (stomach, back, chest, shoulders, and upper arms) was quantified by extraction of SOPP/OPP from an inner, short-sleeve, 100% cotton t-shirt using acetonitrile. Because workers typically wear short-sleeve shirts, arm dosimeters cut from an outer, long-sleeve, 65% polyester/35% cotton shirt long-sleeve shirt, combined as one sample, represent exposure to bare arms. A penetration factor (i.e., the ratio between the outer-shirt torso dosimeter and the inner-shirt torso dosimeter) was also derived – this factor was not used in the dermal exposure calculation, but could be used to determine protection offered by additional clothing layers. Analysis of the three dosimeters (arms, outer-torso, and inner-torso) was done by gas chromatography with flame-ionization detection (GC/FID). Laboratory recoveries averaged approximately 92% and 99% for the long-sleeve cotton-blend shirt and the short-sleeve cotton t-shirt, respectively.

Dermal exposure to the hands was assessed by hand rinses conducted throughout the day when workers would normally wash their hands after coming off the line (i.e., bathroom and lunch breaks). Although thin cotton gloves, finger cots, or fingernail tape are typically worn as an industry practice by sorters and packers to protect their hands from cuts and punctures and to protect the fruit from damage, the study directors asked workers not to wear any hand coverings. Packers at all the pear packing facilities wore thin cotton gloves, finger cots, or fingernail tape, sorters did not; citrus facility #4 was the only facility to have all sorter and packer samples (including pre-sorters) without hand coverings; at citrus facilities 5 and 6, only packers wore cotton gloves – sorters and pre-sorters, with the exception of fingernail tape, did not wear hand coverings. Cotton gloves, when used, were removed prior to the hand rinse procedure (and not included in the sample); fingernail tapes remained. The study notes that the cotton gloves were not intended to nor were effective as a chemical barrier. Hand rinses were collected by rinsing with soap and water over a stainless steel bowl and transferring the solution to a bottle containing sodium chloride. Ethyl acetate was then added to extract the SOPP/OPP. Like the torso and arm dosimeters, analysis was done by GC/FID, with an average laboratory recovery of approximately 112%.

The following table presents a summary of the results for total dermal exposure by facility, crop, and postapplication activity. Results, both the arithmetic mean and the maximum reported exposure, are presented in micrograms and represent exposure over an 8-hour workday. Results shown have been corrected for field fortification recoveries below 100% (including those above 90%).

Table 9: MRID 43432901 – Dermal Exposure Results for Sorters and Packers in Citrus Fruit and Pear Facilities				
Facilities (State)	Crop	Activity	Dermal Exposure (ug)	
			Arithmetic Mean	Maximum
1, 2, 3 (WA)	Pears	Sorter	6134	14102
		Packer	4022	6147
4 (FL)	Citrus	Sorter	2460	3448
		Pre-sorter	7873	12693
		Packer	1500	3088
5, 6 (CA)	Citrus	Sorter	1934	5153
		Pre-sorter	4513	7784
		Packer	720	1845

Inhalation exposure was monitored using a PVC filter in a plastic cassette, followed in series by a silica gel sorbent tube. The filter and tube sample train, placed in the worker's breathing zone on the lapel of their work shirt, was used to collect both particulate and vapor components of SOPP and OPP in the air. The air flow rate was approximately 1 liter per minute using vacuum pumps. Both the filter and tube were desorbed with acetonitrile and analyzed by GC/FID. Laboratory recovery for this method averaged approximately 92%.

The following table presents a summary of the results of the personal air monitoring in all facilities. Results have been corrected for field fortification recoveries below 100% (including those above 90%) and are expressed as a time-weighted average (TWA) in micrograms per cubic meter (ug/m^3). Like dermal exposure, both the arithmetic mean and maximum reported exposure are shown.

Table 10: MRID 43432901 – Inhalation Exposure Results for Sorters and Packers in Citrus Fruit and Pear Facilities				
Facilities (State)	Crop	Activity	Inhalation Exposure (ug/m^3)	
			Arithmetic Mean	Maximum
1, 2, 3 (WA)	Pears	Sorter	95.1	154
		Packer	75.4	96.4
4 (FL)	Citrus	Sorter	19.8	29.8
		Pre-sorter	43.7	50
		Packer	4.6	5.4
5, 6 (CA)	Citrus	Sorter	7.6	27.4
		Pre-sorter	93.2	197
		Packer	6.6	16.7

5.3.2 Postapplication Exposure Assumptions, Factors, and Calculation Methods

The following assumptions and factors were used for assessing the occupational postapplication risks:

- Body weights, dermal and inhalation absorption factors, inhalation rates, hours worked per day, and toxicological endpoints are the same as those used for the occupational handler assessments.
- As with the handler assessment, all exposure durations (short-term and intermediate-/long-term) will be assessed.

- Chemical-specific dermal and inhalation exposure data from MRID 43432901 was used to assess all postapplication risks.
- The cotton gloves described in the study were not chemical-resistant, nor were they intended to be a chemical barrier. Calculation corrections for these gloves were not performed, nor were the gloves analyzed for chemical residue/content.

Dermal and inhalation exposure data was used to quantitatively assess exposure to sorters and packers following SOPP/OPP application. The study data presents inhalation exposure as a TWA concentration in micrograms per cubic meter (ug/m^3) and dermal exposure as a work-day total (8 hours) in micrograms (ug). These concentrations must be converted into an average daily exposure (mg/kg/day) to be used in the MOE calculations described in Section 5.2.3.

To present the inhalation monitoring data as an average daily dose, the following calculation is used.

$$\textbf{Avg Daily Dose}\left(\frac{mg}{kg/day}\right) = \textbf{Daily Exp.}\left(\frac{ug}{m3}\right) \textbf{ x Inhl. Rate}\left(\frac{m3}{day}\right) \textbf{x}\left(\frac{absfactor(\%/100)}{Bodyweight(kg)}\right) \textbf{x}\left(\frac{(1mg)}{(1000ug)}\right)$$

Where:

Average Daily Dose	=	the amount as absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day);
Daily Exposure	=	Personal air monitoring TWA concentration (ug/m^3);
Inhalation Rate	=	Adult daily inhalation rate: 8 hrs/day * 1.6 m^3/hr = 12.8 m^3/day;
Absorption Factor	=	100% for inhalation exposures (all durations);
Body Weight	=	70 kg.

To present the dermal exposure data as an average daily dose, the following calculation is used.

$$\textbf{Avg Daily Dose}\left(\frac{mg}{kg/day}\right) = \textbf{Daily Exp.}\left(\frac{ug}{day}\right) \textbf{ x }\left(\frac{absfactor(\%/100)}{Bodyweight(kg)}\right) \textbf{x}\left(\frac{(1mg)}{(1000ug)}\right)$$

Where:

Average Daily Dose	=	the amount as absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day);
Daily Exposure	=	Dermal exposure during a typical workday (ug/day);
Absorption Factor	=	43% for intermediate-/long-term duration;
Body Weight	=	70 kg.

5.3.3 Occupational Postapplication Risk Estimates

Table 11 below summarizes the postapplication risk estimates for citrus and pear facilities. Short-term risk calculations are shown using both the arithmetic mean and maximum reported exposures; intermediate-/long-term risks are calculated using the arithmetic mean only. Additionally, all dermal risk estimates are calculated with exposures adjusted for the maximum labeled application rate (2% solution). See Table 4 for actual application solutions used in each facility.

There are risks of concern for the following scenarios. Detailed exposure and risk calculations are in Appendix B.

Sorters

- Short-term dermal risk for sorting in pear facilities (MOE = 51). *Note: this risk is calculated with the maximum reported dermal exposure.*

Table 11: Postapplication Risk Estimates for Sorters and Packers in Citrus Fruit and Pear Facilities

Postapplication Activity	Crop (State)	Short-term Risk (Target MOE = 100)				Intermediate-/Long-term Risk (Target MOE = 100*)	
		Dermal MOE		Inhalation MOE		Dermal MOE	Inhalation MOE
		Mean	Max	Mean	Max	Mean	Mean
Pre-sorting	Citrus (FL)	240	150	20000	11000	220	7900
	Citrus (CA)	870	580	5900	2800	790	2300
Sorting	Pears (WA)	120	51	5800	3600	110	2200
	Citrus (FL)	770	550	28000	18000	700	11000
	Citrus (CA)	2200	880	72000	20000	2000	28000
Packing	Pears (WA)	190	130	7300	5700	170	2800
	Citrus (FL)	1300	620	120000	100000	1100	47000
	Citrus (CA)	5500	2400	81000	33000	5000	32000

Note: Dermal risks are calculated with exposures adjusted to the maximum labeled application rate (2% solution). See Table 4 for actual rates used in the study.

*Inhalation MOEs below 1000 may warrant confirmatory inhalation toxicity data. See Table 2.

Postapplication inhalation exposure risks are not of concern for storage room re-entry workers following thermo-fogging applications to pears. Workers performing post-treatment residue sampling likely will enter the storage room shortly after application (i.e., a few hours to a couple of days). At this time, the oxygen level in the storage rooms is 1-3% and the machine's operating instructions require application of a self-contained breathing apparatus (SCBA). Use of SCBA will mitigate any potential concerns for SOPP/OPP inhalation exposure. Additionally, inhalation exposure is considered negligible for those workers entering the storage room months after the application for processing/distribution preparation. The aerosol fog has likely fully dissipated and the room is ventilated to return it to ambient atmospheric conditions.

Postapplication dermal exposure risks for the re-entry workers are considered negligible. Post-treatment residues samplers will contact very few pears and workers preparing the pears for processing and/or distribution will contact the pears months after the application.

5.3.4 Occupational Postapplication Risk Characterization

The data used from the postapplication exposure study is the best available representation of dermal and inhalation exposure to sorters and packers of citrus fruits and pears. Risk calculations using both the arithmetic mean and maximum reported dermal and inhalation exposures for each crop/geographic location are the most conservative estimates. Other statistical manipulations (i.e., median or geometric mean of exposures) may be more representative of actual exposure.

The short-term dermal risk for pear sorters was reported to be a risk of concern (MOE = 51) when the maximum reported dermal exposure for pear sorters was used. However, it should be noted that it is unlikely that this level of dermal exposure would persist over the entire short-term exposure duration (i.e., up to 30 days), and is a conservative risk estimate. The short-term dermal risk using the average of dermal exposure for pear sorters (MOE = 120) may be a more appropriate estimate.

It is recognized that the adjustment of the dermal exposure data for the maximum labeled application rate (2% solution), though typical in HED assessments, is conservative. For some data points this adjustment yields a result approximately 14 times greater than the reported exposure. However, because of a wide variety of uncertainty regarding potential factors influencing exposure, it was assumed that a higher solution concentration would correlate to higher dermal exposures – although, in some cases the data did not exhibit this trend. For example, the data showed that post-harvest workers at pear facilities, while exposed to lower solution concentrations than citrus facility workers in California (0.204% average solution in pear facilities versus 1.03% average solution in the California citrus facilities), the workers in the pear facilities reported higher dermal exposures. This appears to hold true when holding certain observable parameters equal, such as wearing cotton gloves during packing activities (i.e., pear packers wearing gloves exposed to lower concentration solutions reported higher dermal exposures than citrus packers wearing cotton gloves). Additionally, this holds true even when comparing sorters and packers in the pear facilities with pre-sorters in the citrus facilities – because pre-sorters handle the fruits prior to the drying/waxing phase, one may intuitively assume they would have the highest exposures, but they do not. Data for pre-sorters in pear facilities might help refine this discrepancy.

The reasons for these patterns in the data are unclear. As mentioned before, there may be factors influencing the data that were not reported in the study and cannot be determined simply by data observation. Factors such as the ventilation rates within each facility, chemical absorption by cotton gloves, the influence of application method (dip tank, foam, or spray) on chemical/fruit residue, the influence of ambient temperature on the application solutions, the effectiveness of the drying and waxing phases, and the amount of fruit treated (which influences the solution concentration) all may affect exposure, but are indeterminable.

5.3.5 Recommendations for Occupational Postapplication Assessment

Although the label specifying use with the XEDA® Electrofogger requires users to follow the machine's operator instructions, which, in turn, directs re-entry workers to wear SCBA when oxygen levels are low, it is recommended that this provision be directly referenced on the label for workers re-entering the storage room to collect residue samples or perform other early re-entry activities.

It is recommended that sorters (including pre-sorters) and packers of citrus fruits and pears wear chemical-resistant gloves with baseline PPE (i.e., long-sleeve shirt and pants). It was noted in the study that sorters/packers typically wear short-sleeve shirts, so chemical-resistant gloves with arm extensions (instead of a long-sleeve shirt) may be more appropriate. The incident reports, OPP/SOPP's classifications as Category I and II acute dermal irritants, respectively, and the absence of acute toxicity data warrant use of this additional PPE. Currently, some labels require handlers to wear baseline PPE with chemical-resistant gloves and goggles or a faceshield.

6.0 References

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APPENDIX A

Summary of Registered Products
Label Extractions

o-Phenylphenol (PC# 064103)					
Registered Product (% ai)	Crop/Use	App Equipment	Max App Rate (ai)	Max Exposure Time	Comments/Description
The following two products were initially listed for conventional use: • 2792-35: canceled as of 21JUL05 • 43410-9: not labeled for use on citrus or pears (labeled for tomatoes, cucumbers, and peppers only)					
o-Phenylphenol, sodium salt (PC# 064104)					
Deccosol 122 Concentrate Reg No. 2792-28 (14.5%)	Citrus	Wash tank	0.0463 lb ai/gal soln (0.35% soln)	5 minutes	Liquid (SC) PPE - Baseline, gloves, goggles/faceshield
		Bin drencher	0.0066 lb ai/gal soln (0.05% soln)		
	Pears	Wash tank Bin drencher	0.0422 lb ai/gal soln (0.05% soln)	4 minutes	
Stop-Mold "F" Reg No. 43553-20 (22.6%)	Citrus	Mechanical washer	0.0592 lb ai/gal soln (0.6% soln)	4 minutes	Liquid (SC) PPE - not on label
	Pears	Mechanical washer	0.0485 lb ai/gal soln (0.5% soln)	20 seconds	
Foamex Reg No. 64864-54 (14.52%)	Citrus	Spray-type application; apply by spraying over rolling brushes	0.19 lb ai/gal soln/3000 lbs fruit (2% soln)	3 minutes	Liquid (SC) PPE - not on label
		Bin drenchers	0.0285 lb ai/gal soln (0.3% soln)	3 minutes	
SOPP Soap/SOPP Tank Reg No. 64864-45 (13%)	Citrus	spray, flood, dip	0.17 lb ai/gal soln (2% soln)	60 seconds	Liquid (SC) PPE - Baseline, gloves, goggles/faceshield
	Pears	spray, flood, dip	0.17 lb ai/gal soln	30 seconds	

			(2% soln)		
Freshguard 25 Reg No. 8764-1 (25%)	Citrus	Tank/spray washer	0.0411 lb ai/gal soln (0.5% soln)	4 minutes	Liquid (SC) PPE - Baseline, gloves, goggles/faceshield
		Waxing	0.0812 lb ai/gal soln/10000 lbs fruit (1% soln)	Not on label	
	Pears	flood or dip	0.0411 lb ai/gal soln (0.5% soln)	Not on label	
Sta-Fresh 401 Reg No. 8764-24 (1.0%)	Citrus	spray brush applicator	0.133 lb ai/gal soln/10000 lbs fruit RTU Product conc = 0.133 lb ai/gal (1% ai); apply 1 gal/10000 lbs fruit	Not on label	Liquid (SC) PPE - not on label
Freshguard 5 Reg No. 8764-16 (24%)	Citrus	Foam generator, foam washing solution	0.1676 lb ai/gal soln (2% soln)	1 minute	Liquid (SC) PPE - not on label
	Pears	Foam generator, foam washing solution	0.155 lb ai/gal soln (1.86% soln)	30 seconds	
Fresh Foam 26F Foam Cleaner Reg No. 33354-2 (14.15%)	Citrus	Foaming or brushing	0.185 lb ai/gal soln (1.94% soln)	30 seconds	Liquid (SC) PPE - not on label
Steri-Seal "D" Reg No. 57227-7 (22.6%)	Pears	XEDA Fogging machine	0.0633 lb ai/2200 lbs fruit; 0.0234 gal/2200 lbs fruit RTU Product conc = 2.7 lb ai/gal (22.6% ai); apply 3 fl oz/2200 lbs fruit	Not on label	Liquid (SC) PPE - Baseline, gloves, goggles/faceshield

APPENDIX B

Exposure and Risk Calculation

OPP, and salts

Short- and Intermediate-/Long-Term Dermal and Inhalation Handler Exposure Calculations

Exposure Factors		Target MOE
Adult Body Weight - Gen Pop (kg)	70	
ST Dermal NOAEL (mg/kg/day)	100	100*
ST Inhalation NOAEL (mg/kg/day)	100	
IT/LT Dermal/Inhalation NOAEL (mg/kg/day)	39	100*
Dermal absorption factor (use for IT/LT risk only)	43%	
Adult Inhalation rate (m3/hr)	1.6	
Typical work day (hrs/day)	8	
Inhalation absorption factor	100%	
Conversion Factor (ug/mg)	1000	

App Equipment	Crop(s)	Formulation	Daily Area Treated (lbs fruit/day)	Max App Rate (lb ai/lb fruit)	Handler Scenario	Unit Exposure			Daily Dose			ST Risk			IT/LT Risk		
						Dermal (mg/lb ai)		Inhalation (ug/lb ai)	Dermal (mg/kg/day)		Inhalation (mg/kg/day)	Dermal MOE		Inhalation MOE	Dermal MOE		Inhalation MOE
						Baseline	Baseline/Gloves	Baseline	Baseline	Baseline/Gloves	Baseline	Baseline	Baseline/Gloves	Baseline	Baseline	Baseline/Gloves	Baseline
Thermofogger	Pears	RTU	1440000	0.0000288	M/L	2.9	0.023	1.2	1.718126	0.013626514	0.000710949	58	7300	140000	53	6700	55000
Automated spraying, dipping, brushing, foaming	Citrus & Pears	SC/EC	1440000	0.0000633	M/L	2.9	0.023	1.2	3.776297	0.029949943	0.001562606	26	3300	64000	24	3000	25000
					A	Negligible		**see below	Negligible		0.016504686	Negligible		6100	NA		2400
	Citrus	RTU	1440000	0.0000133	M/L	2.9	0.023	1.2	0.79344	0.0062928	0.00032832	130	16000	300000	110	14000	120000
					A'	Negligible		**see below	Negligible		0.016504686	Negligible		6100	NA		2400

*Inhalation MOEs below 1000 may warrant confirmatory inhalation tox data

**Inhalation Exposure from MRID 43432901	
Area (ambient) air monitoring	TWA (ug/m3)
Avg (arithmetic mean) from all data points	38.6
Avg (arithmetic mean) from Facility 6 (highest avg)	90.26

OPP, and salts

Short- and Intermediate-/Long-Term Dermal and Inhalation Postapplication Exposure Calculations

Exposure Factors			
Adult Body Weight - Gen Pop (kg)	70		
ST Dermal NOAEL (mg/kg/day)	100	100**	Target MOE
ST Inhalation NOAEL (mg/kg/day)	100		
IT/LT Dermal/Inhalation NOAEL (mg/kg/day)	39	100**	
Dermal absorption factor (use for IT/LT risk only)	43%		
Adult Inhalation rate (m3/hr)	1.6		
Typical work day (hrs/day)	8		
Inhalation absorption factor	100%		
Conversion Factor (ug/mg)	1000		

Postapplication Activity	Location	Crop	Exposure				Daily Dose				ST Risk				IT/LT Risk	
			Dermal*		Inhalation		Dermal		Inhalation		Dermal MOE		Inhalation MOE**		Dermal MOE	Inhalation MOE**
			(ug ai/day)		(ug ai/m3)		(mg/kg/day)		(mg/kg/day)							
			Mean	Max	Mean	Max	Mean	Max	Mean	Max	Mean	Max	Mean	Max	Mean	Mean
Sorter	WA	Pears	59071.28	136251.21	95.10	154.00	0.84388	1.9464	0.01739	0.0282	120	51	5800	3600	110	2200
	FL	Citrus	9060.77	12699.82	19.80	29.80	0.12944	0.1814	0.00362	0.0054	770	550	28000	18000	700	11000
	CA	Citrus	3237.94	7989.15	7.58	27.40	0.04626	0.1141	0.00139	0.005	2200	880	72000	20000	2000	28000
Packer	WA	Pears	37419.93	53452.174	75.39	96.40	0.53457	0.7636	0.01378	0.0176	190	130	7300	5700	170	2800
	FL	Citrus	5525.672	11373.849	4.56	5.43	0.07894	0.1625	0.00083	0.001	1300	620	120000	100000	1100	47000
	CA	Citrus	1271.112	2860.4651	6.75	16.70	0.01816	0.0409	0.00123	0.0031	5500	2400	81000	33000	5000	32000
Pre-sorter	FL	Citrus	28996.32	46751.381	26.95	50.00	0.41423	0.6679	0.00493	0.0091	240	150	20000	11000	220	7[illegible]
	CA	Citrus	8029.353	12068.217	93.23	197.00	0.11471	0.1724	0.01705	0.036	870	580	5900	2800	790	23[illegible]

*Dermal exposures are adjusted to the maximum labeled application rate of 2% solution

**Inhalation MOEs below 1000 may warrant confirmatory inhalation tox data

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R115680

Chemical:	**o-Phenylphenol; o-Phenylphenol, sodium salt; o-Phenylphenol, potassium salt; (1,1'-Biphenyl)-2-ol, ammonium salt**
PC Code:	**064103; 064104; 064108; 064116**
HED File Code	***14000 Risk Reviews***
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File ID:	**DPD319636**
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